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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,677	08/16/2001	Donald E. Weaver	NCI-006DV1	5945

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/932,677

Applicant(s)  
Weaver et al.

Examiner  
Deepak Rao

Art Unit  
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 16, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 68-140 ☐ are pending in the application.
- 4a) Of the above, claim(s) 70-77, 79, 81-91, 94-117, and 120-137 ☐ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68, 69, 78, 80, 92, 93, 118, 119, and 138-140 ☐ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20) ☐ Other:

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## DETAILED ACTION

Claims 68-140 are pending in this application.

### *Election/Restriction*

Applicant's election without traverse of the species 3-amino-3[3-(4-chlorophenoxy)-phenyl]-propionic acid is acknowledged. Applicant indicated that claims 68-69, 78, 80, 92-93, 118-119 and 138-140 read on the elected species.

The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the merits on the elected claims would be final.**

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

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Upon a search conducted based on the elected species to the extent on the compounds of formula  $RCH(NH_2)CH_2COOH$  wherein R is phenyl(substituted), art was found. As the elected species was found to be unpatentable, based on the guidelines of MPEP § 803.02, the Markush-type claims were examined to the extent of the searched subgenus. Accordingly, claims 70-77, 79, 81-91, 94-117 and 120-137 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. The non elected species and the generic subject matter drawn to the non elected species from claims 68-69, 78, 80, 92, 93, 118, 119 and 138-140 is also withdrawn from further consideration.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-69, 78, 80, 92, 93 and 138-140 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method of use of substituted  $\beta$ -alanine compounds represented by a formula (as shown in claim 68) wherein both the  $\alpha$  carbon and the  $\beta$  carbons are disubstituted by  $R^1$  which is defined to be H, alkyl, aryl, etc. The specification however does not

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adequately support the instantly recited generic group of compounds. First, the formula of claims 68 and 138 added by preliminary amendment was not found anywhere in the specification and there is no generic support for the instantly recited structural formula having the diverse combinations of the substituents. The specification on page 14, lines 26-29 provides an example for a ' $\beta$ -amino anionic compound represented by the formula  $A-CHR'CHR'-NR_aR_b$  wherein  $R'$  is H or alkyl. However, there is no disclosure of disubstitution at both the  $\alpha$  and  $\beta$  carbons. The specification on page 20, lines 6-11, provides that the compound used in the method can be selected from ' $\alpha, \alpha, \beta, \beta$ -tetrasubstituted  $\beta$ -alanines', however, does not specify the substituents. All the exemplified compounds in Tables 1-3 are monosubstituted at the  $\beta$ -carbon only (see e.g., the elected species), which are insufficient to provide support for the instantly recited genus. Further, in the definition of A, it is recited "a prodrug form thereof", however, no adequate support for the instant recitation is found. The specification does not provide any help as to which functional groups are intended to be derivatized to form the instantly recited "prodrugs". Many functional groups are capable at least in theory to being derivatized. Accordingly, it is deemed that the instant claims are not adequately supported by the description in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 68-69, 78, 80, 92-93, 118-119 and 139-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 68, in line 2 it is recited "a substituted  $\beta$ -alanine compound" and the corresponding formula is shown at line 4 wherein A is defined to be "an anionic group at physiological pH" which group according to the specification includes sulfate, sulfonate, etc. (see page 14, lines 12-20). However, a  $\beta$ -alanine compound must have a carboxylate group at the 1-position and an amino group at the 2-position. When A is other than a carboxylate group, the compound is no longer a  $\beta$ -alanine compound and therefore, it is not clear how the claimed group of compounds are referred to as  $\beta$ -alanine compounds.
2. Claim 78 recites the limitation "said aryl or said aryloxy group is substituted" in line 2. There is insufficient antecedent basis for this limitation in claims 69 or 68 on which the claim is dependent. The base claim does not recite any of the groups to be further substituted. Claim 80 also contains the same discrepancy.
3. Claims 118 and 119 recite several substituted phenyl groups in the definition of R, see e.g., 3-(4-chlorophenoxy)phenyl, etc. There is insufficient antecedent basis for these substituted phenyl groups in the base claims 68 or 69. The independent claim does not recite that aryl group is further substituted.

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4. In claim 139, line 2, the recitation "or a derivative, analog" is not understood. The claim already recites 'substituted or unsubstituted  $\beta$ -alanine compound' and therefore, it is not clear what else is intended by the instant recitation.
5. Claim 140 recites the limitation "said uracil" in line 1. There is insufficient antecedent basis for this limitation in claim 139 or 138 on which claim 140 is dependent. The base claim does not contain any disclosure related to uracil derivatives.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68-69, 78, 80, 92-93 and 138-140 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver et al., WO 98/40055. The reference discloses method of inhibiting epileptogenesis and treating convulsive disorders, see the disclosure in page 2. Further, the reference discloses  $\beta$ -aryl- $\beta$ -alanine compounds disclosed in these methods, see the compounds disclosed in Table 2.

**Note:** The instant claims do not meet the requirements of 35 U.S.C. 112, first paragraph and therefore are not entitled for the priority dates claimed.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 68-69, 78, 80, 92, 93, 118 and 119 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-19 of U.S. Patent No. 6,306,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference also teaches same method use of analogous compounds. The reference teaches a method of inhibiting epileptogenesis using a  $\beta$ -amino compound, see claim 18. The instantly recited substituted  $\beta$ -alanine compound is subgenus of the reference compounds. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.



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Receipt is acknowledged of the Information Disclosure Statement filed on January 16, 2002 and a copy is enclosed herewith.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Deepak Rao  
April 5, 2002